

REMARKS

New claims 30 and 31 have been added directed to eicosapentaenoic acid 20:5 ω 3 and docosahexaenoic acid 22:6 ω 3 being derived from fish oil. The basis for these claims can be found on page 8 at lines 16-18 of the disclosure.

Claims 1,2, and 5-11 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Applicant respectfully traverses on the basis of the amended claims and the following comments. Claim 1 has been amended to clarify that the sterol and the omega-3 fatty acid together form an ester. The basis for this amendment can be found, for example, on page 4 at lines 5-9. Thus, it is now clear that the applicant is claiming a nutritional supplement comprising a sterol ester of an omega-3 fatty acid. In view of amended claim 1, claim 2 has been cancelled and claims 5-11 have been amended to depend from claim 1.

Claims 1, 2 and 5-11 stand rejected under 35 U.S.C. 103 for being unpatentable over Miettinen,et.al. (EPA 594,612) in view of Leaf,et.al. (The New England Journal of Medicine, Vol. 318, No. 9, pages 549-557). The Applicant respectfully traverses having regard to the amended claims and the following comments.

Miettinen,et.al., is directed to a serum cholesterol lowering composition comprising β -sitostanol. Nowhere in Miettinen is there a teaching or even a suggestion that triglyceride levels are reduced along with a reduction in serum cholesterol. Nowhere

does the reference teach or suggest that the specific fatty acids disclose and claimed in the instant application could be esterified with a sterol to form a composition which lowers both cholesterol and triglyceride levels.

The disclosure of Miettinen,et.al. (page 4, lines 40-45) refers to the addition of monoenes or polyenes to enhance the lowering of cholesterol. The teachings of this reference on page 4 at lines 57-58 suggest that any C₂-C₂₂ fatty acids could be used to esterify the β -sitostanol. There is no suggestion at all that triglyceride levels would be lowered. Since the entire reference is directed to lowering cholesterol levels, one-skilled in the art would be fairly led to the conclusion that esterification of the β -sitostanol is done in this reference for the sole purpose of enhancing the cholesterol lowering effect. This would lead the sale skilled workman away from concluding that esterifying a stanol or sterol with a fatty acid will result in a composition that also has the effect of lowering triglyceride levels. Therefore, there would be no motivation for the skilled workman to believe that a sterol ester of a fatty acid, particularly the fatty acids recited in claim 1, would have a triglyceride lowering effect.

Furthermore, while Miettinen,et.al. may teach that β -sitosterol when esterified with a C₂-C₂₂ fatty acid is an effective cholesterol-lowering agent, those skilled in the art understand that the role of the fatty acid moiety of a phytosterol-fatty acid conjugate is to improve its solubility in lipid-based food material. No additional function

is generally considered because phytosterol esters are poorly absorbed by the digestive tract. Since omega-3 fatty acids must enter the blood circulation in order to exert an effect on triglyceride levels, it is not obvious that this will be so when they, in part, form a molecule that is not greatly absorbed. In contrast, the Applicant in the present application teaches that the omega-3 fatty acids lower triglyceride levels when provided a phytosterol ester format.

Leaf,et.al., does not alleviate the deficiencies of Miettinen et.al.; Leaf,et.al., teaches that unesterified omega-3 fatty acids lower serum triglyceride levels. There is no teaching or suggestion in this reference that esterified forms of the omega-3 fatty acids would have the same or similar effect. Changes in the chemical structure of a compound may have a profound influence on how the compound behaves in the body. Therefore, it is not obvious to one skilled in the art that an ester (particularly a sterol ester) of an omega-3 fatty acid would have the same or similar triglyceride lowering effect as the omega-3 fatty acid alone.

Since Miettinen,et.al. appears to teach away from triglyceride lowering effects of β -sitostanol fatty acid esters, and since there is no basis in Leaf,et.al., to conclude that esters of omega-3 fatty acids would have a triglyceride lowering effect, one skilled in the art would have no motivation to combine the teachings of Miettinen,et.al. and Alexander, et.al. to obtain the claimed invention.

Serial No. 09/385,834

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The Examiner states on page 5 of the Office Action that:

It is a prima facie case of obviousness for one skilled in this art to use in combination two or more compositions that have been used separately for the same purpose in order to form a third composition useful for the same purpose.

The Applicant respectfully disagrees that he has simply combined two separate compositions to form a third. The Applicant submits that he has reacted one compound with another to form a different compound, and said different compound is then used in a composition. One skilled in the art understands that a new compound formed in such a reaction has different properties from either of the two starting compounds. Particularly in relation to biological activity, it is not prima facie obvious that the new compound will possess the same or similar properties to either one or both of the starting compounds. Therefore, the Applicant submits that a prima facie case for obviousness has not been established by the Examiner in regard to amended claim 1, which recites a nutritional supplement comprising an ester of sterol and an omega-3 fatty acid.

In view of the amendment made to claim 1 and the preceding remarks, the Applicant submits that the claimed invention is patentably distinct over the cited references and respectfully requests that the rejection be withdrawn.

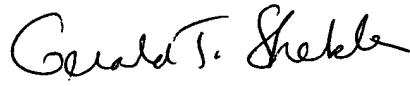
With the above amendments and remarks, this application is considered ready for allowance. Should the Examiner be of the opinion that a telephone conference

Serial No. 09/385,834

would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below-listed number.

Respectfully submitted,

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